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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,322	02/28/2002	Abbot F. Clark	1910	8526

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EXAMINER
ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/07/2006

Alcon, Inc.
c/o Alcon Research, Ltd.
Patrick M. Ryan(Q-148), R&D Councel
6201 So. Freeway
Fort Worth, TX 76134-2099

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,322	CLARK, ABBOT F.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2-28-02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I in the reply filed on 1-17-2006 is acknowledged. The traversal is on the ground(s) that both GLC1A and CYP1B1 are glaucoma genes and the same antibiotic compositions are used to overcome premature stop mutations in both genes. Applicant's argument has been fully considered and deemed persuasive. Hence the requirement is withdrawn.

Claims 1-10 are pending and currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using aminoglycoside antibiotics to treat glaucoma caused by a premature stop mutations in a gene, does not reasonably provide enablement for using aminoglycoside antibiotics to treat any other ophthalmic disease caused by a premature stop mutations in a gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re* Wands 858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988). The court in

Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is "undue", not "experimentation" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7), the predictability or unpredictability of the art, and (8) the breadth of the claims. While all these factors are considered, those used in determining the lack of enablement are discussed below.

The instant claims are drawn to methods of treating ophthalmic diseases caused by premature stop mutations in a gene by the administration of aminoglycoside antibiotics.

The specification is silent with regard to what ophthalmic diseases (if any) other than glaucoma are caused by premature stop mutations in a gene. The specification is equally silent as to what other ophthalmic diseases could be treated by the administration of aminoglycoside antibiotics. Moreover, the working examples are lacking. While the skill in the arts of medicine, pharmacology and immunology is high, to date, prediction of therapeutic efficacy for any given composition for a given disease is quite unpredictable. Consequently, one of skill in the art would not be able to contemplate which "ophthalmic disease caused by premature stop

mutations" would be an effectively treated utilizing aminoglycoside antibiotics nor could he contemplate what "ophthalmic diseases" could be effectively treated by either systemic administration or via contact with the ocular surface of said antibiotics. Given the lack of success in the art, the lack of working examples and the unpredictability of therapeutic efficacy, the specification, as filed, does not provide enablement for methods of using aminoglycoside antibiotics to treat ophthalmic diseases caused by premature stop mutations for the full scope of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2, 4-5 and 7-8 are rejected under 35 U.S.C. 102(a) as being anticipated by Miller et al. (Journal of the American Animal Hospital Association, 2000, Vol. 36 No. 5, pages 431-438) in light of Alward et al. (New England Journal of Medicine, 1998, Vol. 338 No. 15, pages 1022-1027).

The instant claims are drawn to methods of treating an ophthalmic disease caused by premature stop mutations in a gene (glaucoma) by administering a composition comprising an aminoglycoside antibiotic compound (gentamicin) wherein said composition can be topically administered as an eye drop.

Miller et al. disclose methods of using a composition comprising gentamicin to treat glaucoma in dogs (see abstract). Miller et al. further disclose that said composition is topically administered to the eye as an eye drop (see page 432, right hand column). Alward et al. disclose glaucoma is associated with stop mutations in the GLC1A gene (see abstract and Table 4 on page 1026). Consequently, Miller et al. anticipates the limitations of the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (Journal of the American Animal Hospital Association, 2000, Vol. 36 No. 5, pages 431-438) and Barton-Davis et al. (Journal of Clinical Investigation, 1999, Vol. 104 No. 4, pages 375-381 – IDS filed 2-28-2002) in light of Alward et al. (New England Journal of Medicine, 1998, Vol. 338 No. 15, pages 1022-1027).

The instant claims are drawn to methods of treating an ophthalmic disease caused by premature stop mutations in a gene (glaucoma) by administering a composition comprising an aminoglycoside antibiotic compound (gentamicin) wherein said composition can be topically administered as an eye drop.

Miller et al. disclose methods of using a composition comprising gentamicin to treat glaucoma in dogs (see abstract). Miller et al. further disclose that said composition is topically administered to the eye as an eye drop (see page 432, right hand column). Consequently, Miller et al. anticipates the limitations of the instant invention. Alward et al. disclose glaucoma is associated with stop mutations in the GLC1A gene (see abstract and Table 4 on page 1026). Consequently, Miller et al. anticipates the limitations of the instant invention.

Miller et al. differs from the instant invention in that they don't explicitly disclose the recited antibiotic concentrations recited in claims 9-10 nor do they explicitly disclose that the patients have been diagnosed with the recited gene mutations. However, since Miller et al. disclose the use of gentamicin to treat glaucoma, it would have been obvious for the skilled artisan to optimize its concentration. It is deemed that this optimization would necessarily encompass the recited concentrations. With regard to the determination of the specific etiology of the glaucoma (i.e. the specific mutation), it is deemed that this would necessarily be part of any treatment regiment. Consequently, the recited reference renders all the limitations of the instant claims obvious.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ROBERT ZEMAN
PATENT EXAMINER

March 30, 2006